K011342

JUL - 9 2001

Summary of Safety & Effectiveness
Beckman Coulter™ COULTER® LH 750 hematology analyzer

1.0 **Submitted By:**

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2.0 **Date Submitted:**

April 30, 2001

3.0 **Device Name(s):**

3.1 **Proprietary Names**

Beckman Coulter™ COULTER® LH 750 Hematology Analyzer

3.2 **Classification Name**

Automated differential cell counter (21 CFR §864.5220)

4.0 **Predicate Devices**

Candidate(s)	Predicate	Manufacturer	Docket No.
COULTER LH 750	COULTER GEN•S System	Beckman Coulter	K962988^ K993356#
LH 750 WBC and NRBC parameters	CELL-DYN®* 4000 WBC and NRBC parameters	Abbott Diagnostics**	K961439
LH 750 NRBC parameter	Manual Reference Smear	Not applicable	NCCLS H-20A

^ COULTER GEN•S System
# COULTER Hematology Analyzers with IRF and MRV Parameters
*Trademark of Abbott Diagnostics
**5440 Patrick Henry Drive, Santa Clara, CA.

Other Reference Methods

Candidate(s)	Method	Reference
LH 750 Platelet	RBC/Platelet Ratio Method	ICSH/ISLH+

+Am. J Clin. Pathol. 2001:115, 460-464

5.0 **Description:**

Information is provided demonstrating that Beckman Coulter's COULTER® LH 750 hematology analyzer is substantially equivalent to products curently in commercial distribution (COULTER GEN•S & Abbott CELL-DYN 4000) and introduces an NRBC parameter for in vitro diagnostic use.

6.0 **Intended Use:**

The COULTER® LH 750 hematology analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for in vitro diagnostic use in clinical laboratories. The system also provides automated reticulocyte analysis and enumeration of nucleated red blood cell (NRBCs).

7.0 Comparison to Predicate(s):

The following tables show similarities and differences of LH 750 with predicates identified in Section 4.0 of this summary.

Similarities to the GEN•S System Predicate

GEN•S System	LH 750
Red blood cell/platelet method: Impedance, Triplicate Counts, Extended Analysis Time for Cytopenic Samples, Log Curve Analysis	Same as GEN•S
Reticulocyte method: laser light scatter and nucleic acid dye (New Methylene Blue)	Same as GEN•S
Interfering substances on WBC, RBC & PLT count	Same as GEN•S
Offers following reportable parameters: WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, PLT, MPV, lymphocyte #&%, monocyte #&%, neutrophil # &%, eosinophil #&%, basophil #&%, reticulocyte #&%, graded RBC morphology, IRF, MRV	Same as GEN•S

Similarities to the CELL-DYN 4000 Predicate

CELL-DYN 4000	LH 750
Automated differential cell counter	Same as CELL-DYN 4000
Parameters calibrated: WBC, RBC, Hgb, MCV, PLT, MPV	Same as CELL-DYN 4000
Offers following reportable parameters: WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, PLT, MPV, NRBC #&%, retic #&%, IRF, neut #&%, lymph #&%, mono #&%, eo #&%, baso #&%	Same as CELL-DYN 4000

Differences with the GENS Predicate

GEN•S System	LH 750
Requires manual specimen presort	Has Random Access capability
WBC Linearity extends to 140,000 cells.	WBC Linearity extends to 400,000 cells.
Platelet analysis generated a suspect flag in the presence of algorithm limitations.	Improved platelet algorithm
No NRBC enumeration	Has NRBC enumeration
Generated a suspect flag in the presence of suspected interference	Corrected WBC result in the presence of suspected interference
Results on diluted samples are manually calculated	Has Predilute capabilities; autocalculation of diluted samples

Differences with the CELL-DYN 4000 Predicate

CELL-DYN 4000	LH 750
WBC method uses optical scatter/fluorescence technology	WBC method uses Impedance
RBC/PLT method uses 2-D optical scatter & focused flow impedance	RBC/PLT method: Impedance
Reticulocyte method uses optical scatter & fluorescence technology	Reticulocyte method uses laser light scatter and nucleic acid dye (NMB)
Hemoglobin method uses cyanide-free absorption spectrophotometry	Hemoglobin method uses modified Cyanmethemoglobin
CD61 (immuno-platelet)	No immuno platelet method
No MRV analysis	Reports MRV parameter

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence studies of the COULTER® LH 750 Hematology Analyzer to products already in commercial distribution.

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Re: K011342
Trade Name: Beckman Coulter™ COULTER® LH 750 Hematology Analyzer
Regulation Number: 21 CFR § 864.5220
Regulatory Class: III
Product Code: GKZ
Dated: April 30, 2001
Received: May 2, 2001

Dear Dr. Sugrue:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K011342

Device Name: **COULTER® LH 750 Hematology Analyzer**

Indications for Use:

The COULTER® LH 750 is a quantitative, automated hematology analyzer For In Vitro Diagnostic Use in clinical laboratories. The LH 750 System provides automated complete blood count, leukocyte differential and Reticulocyte analysis and nucleated red blood cell (NRBC) enumeration.

Future commercialization will add ISOTON® 4 diluent /Lyse S® 4 Lytic reagent to the indications for use.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K011342

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96